IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	)	Civil Action No. 05-340 KAJ
THIS DOCUMENT RELATES TO: ALL ACTIONS C.A. Nos. 05-340, 05-404 and 05-605	)	Hon. Kent Jordan, U.S.D.J.

DIRECT PURCHASER PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' CONSOLIDATED MOTION TO DISMISS (REDACTED)

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I. INTRODUCTION

A. Defendants' Overall Scheme To Monopolize

Direct Purchaser Plaintiffs[1] ("Plaintiffs") have overpaid for fenofibrate (TriCor's active ingredient) because Abbott and Fournier ("Defendants") maintained their monopoly power in the fenofibrate market by unlawfully impeding generic competition.

Defendants' motion to dismiss is premised on two false assumptions -- that all of their alleged acts (a) are "lawful" in isolation, and (b) are challenged here solely because they are part of an overall scheme. While the Supreme Court and Third Circuit have clearly held that a scheme comprised entirely of independently lawful acts can be actionable under § 2 of the Sherman Act (see pp. 41-43 infra, citing cases), Direct Purchaser Plaintiffs have alleged far more than that here.

Specifically, Plaintiffs allege a carefully orchestrated, overarching scheme by Defendants to impede generic competition to TriCor, consisting of numerous interconnected acts, each of which is illegal by itself because each was an act by monopolists to willfully maintain a monopoly. See Section II.B., below, citing, e.g., LePage's v. 3M, 324 F.3d 141, 155 (3d Cir. 2003) (en banc) ("the courts must look at a monopolist's conduct taken as a whole rather than considering each aspect in isolation"). While each of these acts is independently unlawful, Supreme Court and Third Circuit law mandates that such interconnected acts be analyzed as a whole, rather than in isolation. Id. When viewed together, there can be no doubt that Defendants' scheme was unlawfully exclusionary

[1] This brief is jointly submitted by the Coordinated Direct Purchaser Plaintiffs. "Complaints" refers, collectively, to the amended complaints filed in Louisiana Wholesale Drug Co. Inc., et al. v. Abbott Laboratories, et al., No. 05-cv-340 (KAJ) ("DPC Cpt."); Walgreen Co. et al. v. Abbott Laboratories, et al., No. 05-cv-404 (KAJ) ("Walg. Cpt."), and CVS, et al. v. Abbott Laboratories, et al., No. 05-cv-605 (KAJ) ("CVS Cpt.").

under §2 because the purpose and effect of the scheme and each of its component parts was to erect artificial barriers to entry by generic competitors. The Hatch-Waxman Act and State generic substitution laws were specifically designed to promote generic entry in order to prevent brand manufacturers such as Abbott from exploiting a significant imperfection in the pharmaceutical market—i.e. that those who choose which drug is appropriate (doctors) do not pay for the drugs. By impeding generic entry through exclusionary means, Defendants have been able to exploit that imperfection and maintain their monopoly.

The scheme alleged in the Complaints includes the following interrelated exclusionary acts:

(a) Upon coming to market with the TriCor capsule product, in anticipation of imminent competition from generic capsule versions of TriCor, Defendants intentionally developed a new form of TriCor that, while medically equivalent to the prior form, would not be AB-rated to—and therefore could not be automatically substituted by—the soon-to-be-approved generic capsules because it had a different dosage form and strength than the capsules;

(b) Defendants knowingly filed baseless patent infringement lawsuits, falsely alleging that the generic capsules infringed Defendants' capsule patent, in order to delay FDA approval of the generic capsules for up to 30 months, thereby buying time for their planned conversion of TriCor demand from the capsules to the tablets before the generic capsules could enter the market;

(c) Upon receiving FDA approval of their new tablet form of TriCor, Defendants took various steps to force the conversion of TriCor demand from the capsule form to the new tablet form, before generic capsules could enter the market. These steps included: (i) falsely promoting the tablets as an improvement over the capsules (in contravention of their representations to the FDA that the products were bioequivalent); (ii) "bleeding down" the inventory of TriCor capsules, so that all TriCor prescriptions would have to be filled with TriCor tablets (which did not face imminent generic competition); and (iii) listing the TriCor capsules as "obsolete" in the National Drug Data File ("NDDF") which, as explained below, impeded pharmacists' ability to substitute cheaper generic capsules for more expensive branded TriCor; and

(d) After generic manufacturers Teva and Impax predictably responded to Defendants' scheme by developing generic versions of the TriCor tablets, Defendants repeated the entire exclusionary process by (i) developing and obtaining FDA approval for yet another form of TriCor that was medically equivalent, but not AB-rated, to the generic

tablets; (ii) filing baseless patent litigation to automatically delay FDA approval of the generic tablets for up to 30 months; and (iii) minimizing the sales that generic versions of TriCor could obtain by repeating their previously successful efforts to force a prompt and massive conversion to the new form of TriCor that did not face imminent generic competition.

As detailed further below, there is nothing "lawful" about any of these acts – whether viewed in isolation or together. All of the acts are unlawful, alone or together, because they were all exclusionary acts committed by monopolists to maintain a monopoly.

B. Defendants' Motion to Dismiss

Defendants' motion to dismiss hinges on the following two arguments:

(1) that as a **factual** matter, Plaintiffs purportedly admitted that Defendants' new forms of TriCor were improvements over the prior versions. This mandates dismissal, Defendants argue, because antitrust claims involving product changes are (in Defendants' view) actionable only if the new product was no "improvement" over the prior version (Dfts Bf at 9–14); and

(2) that as a **legal** matter, if a competitive product can get to market at all – i.e., if Defendants' exclusionary tactics do not totally foreclose all competition – then the conduct is not illegal. Under Defendants' view, since Teva's product got 5% of fenofibrate sales, Defendants' scheme was not exclusionary (even though it let them maintain 95%) of the relevant market and thereby caused artificially inflated fenofibrate prices). (Dfts Bf at 9–14).

Defendants' arguments are wholly without merit. First, Defendants wove out of whole cloth Plaintiffs' supposed "admission" that the first tablet was an improvement over the existing TriCor capsule. Plaintiffs specifically allege that the change to the tablets "offered no benefits of any kind to consumers." CVS Cpt. at ¶50; see also Walg. Cpt. at ¶52; DPC Cpt. at ¶80. Plaintiffs' allegations in this regard are plain and unmistakable. See, e.g., CVS Cpt. at ¶18 (change to tablets "deliver[ed] no benefits to patients"); id. at ¶58 (tablets "offered no new benefits to consumers").[2] Thus,

[2] Indeed, Plaintiffs allege "the introduction of [the tablets] was disadvantageous to patients . . (continued...)

Plaintiffs' allegations, which must be accepted as true on this motion, directly contradict the fundamental factual premise of Defendants' motion. The motion can therefore be denied without further inquiry. Nevertheless, Plaintiffs will show below how their allegations also meet alternative (and in Plaintiffs' view, more appropriate) legal standards for evaluating exclusionary effects in cases involving product changes. See infra pp. 23-27 .

Second, Defendants' contention that an exclusionary scheme is lawful unless it completely forecloses competition is directly contrary to Third Circuit law. See, e.g., U.S. v. Dentsply Int'l Inc., 399 F.3d 181, 191 (3d Cir. 2005) ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."); LePage's, 324 F.3d at 155. As these controlling cases make clear, the relevant standard is whether an exclusionary scheme substantially injures competition, not whether it forecloses competition altogether. Plaintiffs' allegations easily meet this standard. See infra at pp. 44-45.

For these and other reasons, as shown below, Defendants' motion to dismiss must fail.

II. STATEMENT OF FACTS

A. The Drug Approval Process

In 1984, Congress amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301-392) by enacting the Hatch-Waxman Act. A primary goal of the Act was to address the rising cost of prescription drugs by encouraging the safe and fast development and approval of generic versions of brand drugs. See CVS Cpt. at ¶20; In re Barr Labs Inc., 930 F.2d 72, 76 (D.C. Cir. 1991)

(continued...)

. because of the well-documented likelihood of patient confusion inherent in changing patients from one medication to another having a different dosage strength." CVS Cpt. at ¶58 (emphasis added).

("Congress sought to get generic drugs into the hands of patients at reasonable prices fast."). The Act simplified the regulatory hurdles for generic companies by permitting them to file Abbreviated New Drug Applications ("ANDAs") with the FDA, relying on safety and efficacy data submitted by the proposed generic's brand-name counterpart in its New Drug Application ("NDA"). The Act also lengthened patent protection for certain brand drugs, and streamlined the process by which brand companies could enforce their patents against generic companies. See CVS Cpt. at ¶¶ 19–23; Walg. Cpt. at ¶¶ 22–26; DPC Cpt. at ¶¶ 31–40. Thus, Congress struck a balance between the rights of patent holders and the public's interest in safe, effective and low-cost drugs.

Congress enacted the Hatch-Waxman Act shortly after every State, with the aid of the FDA and Federal Trade Commission, enacted generic substitution laws permitting (or requiring) pharmacists to dispense generics in lieu of brands whenever possible. See pp. 9-11, below. This regulatory regime has been a great success. The first generic competitor to enter the market typically does so at a price at least 30% below that of the brand, and the discount increases to as much as 90% as additional generics enter. See CVS Cpt. at ¶22; see also Cong. Budget Off., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 28-31 (July 1998) ("CBO Study"); Kirking, et al., *Economics and Structure of the Generic Pharmaceutical Industry*, 41 J. Amer. Pharm. Assoc. 578, 579 (2001).[3] Because of these price differences, generics quickly capture as much as 90% of the brand drug's pre-generic sales. See CVS Cpt. at ¶22.

[3] To the extent that Plaintiffs include citations in this fact section beyond the Complaints, those citations are generally for background purposes and/or are to judicial decisions or administrative reports of which the Court may take judicial notice on a motion to dismiss. See, e.g., In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003).

Regulatory barriers to generic entry, however, provide opportunities for brand companies to "game the system" and wrongfully extend the monopoly granted by their patents. Defendants' scheme here centers on the misuse and abuse of two of these regulatory barriers: (1) the Hatch-Waxman 30-month stay; and (2) the FDA regulations for granting an "AB-rating" to a generic drug, which rating permits (and often requires) pharmacists to be substitute the generic for the brand.

1. The 30-Month Stay

Great potential for abuse comes from the Hatch-Waxman Act's 30-month stay provision, which is intended to protect a brand company's legitimate patents by providing a "grace period" during which infringement claims may be adjudicated. Under this provision, if a brand company brings timely patent litigation against a potential generic competitor, the FDA is automatically stayed from approving the proposed generic product for up to 30 months, without inquiry into the validity of the patent or the merit of the suit. This provides the opportunity for brand companies to delay generic entry simply by filing patent suits, even if they are baseless. See CVS Cpt. at ¶ 27; Walg. Cpt. at ¶ 30; DPC Cpt. at ¶ 39.

This type of abuse forms one part of Defendants' scheme here. By filing baseless patent suits solely to obtain multiple 30-month stays, Defendants delayed generic competition long enough to execute their exclusionary market conversions, as detailed further below.

2. FDA Approval and the AB-Rating System

The need to obtain FDA approval is a significant barrier to generic entry in the pharmaceutical industry. See Geneva Pharm., Inc. v. Barr Lab. Inc., 386 F.3d 485, 499 (2d Cir.

2004). Further, under the Hatch-Waxman Act and State regulatory regimes, described below, only generic drugs that have been "AB-rated" by the FDA may be automatically dispensed by the pharmacist in lieu of the brand drug. In order to receive an AB-rating, a generic drug must be: (1) therapeutically equivalent to its brand name counterpart, meaning that the generic has the same active ingredient, form, dosage, strength and safety and efficacy profile, and (2) bioequivalent to its brand name counterpart, meaning that the generic is absorbed in the body at approximately the same rate as is the branded drug. See DPC Cpt. at ¶¶ 41.

As shown below, as part of their exclusionary scheme, Defendants developed and obtained approval for a new tablet form that was not an improvement over the capsule. But because the new tablet had a slightly different dosage form and strength, the soon-to-be-approved Teva and Impax capsules could not be AB-rated to it. Defendants knew, based on the economics of the pharmaceutical industry and the AB-rating system, that this tactic would substantially impede competition from generic capsules, and thus allow Defendants to maintain their TriCor monopoly. Defendants' unlawfully exclusionary conduct allowed them to maintain their monopoly by impeding the generic entry that the Hatch-Waxman Act was designed to foster.

B. The Economics of Pharmaceutical Marketing

The anticompetitive effect of Defendants' conduct is thrown into sharp focus when viewed against the economic realities of the pharmaceutical marketplace.

In efficient markets, price plays an important role in product selection because the person selecting the product also pays for the product. CVS Cpt. at ¶ 10. The pharmaceutical market is fundamentally different. The person selecting the product – the doctor – does not pay for the product. Id. at ¶ 12. There is, thus, a "price disconnect" that prevents the market from functioning

efficiently: "The basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescriptions." Drug Product Selection, Staff Report to the FTC (Jan. 1979) ["FTC Staff Rep."] at 2-3; see also A. Masson and R. Steiner, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS ["Generic Substitution"] at 5 (FTC 1985) ("[T]he institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician.");[4] CVS Cpt. at ¶¶11-12. Not having the obligation to pay for the products, physicians have little if any incentive to even consider price in their product selections. FTC Staff Rep. at 64-65; Generic Substitution at 6; CVS Cpt. at ¶ 12.

Brand-name companies such as Abbott exploit this market defect by heavily promoting their brand products to doctors. See CVS Cpt. at ¶ 12. Brand companies typically spend 20-30% of their sales revenue on promotion, an amount that exceeds their research and development budgets by a factor of 2-4. FTC Staff Rep. at 32. Almost 70% of a typical brand company's promotional budget is spent on "detailing," *i.e.*, direct person-to-person promotion to the doctor. *Id.* at 59. These detailers promote branded products not on the basis of price, but solely on the basis of efficacy. Id. at 60; CVS Cpt. at ¶ 12. Absent generic competition, the combination of the price disconnect and heavy brand promotion to doctors results in "extend[ing] the [brand] drug's dominance even after the expiration of the patent which conferred the initial legal monopoly." Generic Substitution at 6;

[4] Relevant portions of these texts are included in Direct Purchaser Plaintiffs' Compendium of Unreported Cases and Other Authorities.

CVS Cpt. at ¶14.[5]

Generic companies market products in a fundamentally different way. Rather than exploit the market defect by promoting products to doctors, generic companies market to pharmacies based principally on price. CVS Cpt. at ¶13; FTC Staff Rep. at 49-50. They do so not out of altruism, but necessity. A company cannot profitably promote a generic product to doctors because it would have no assurance that a pharmacist would dispense its generic product rather than another's. Id. at ¶50. It is thus impossible for generic companies to exploit the price disconnect by promoting products to doctors, so they must try to increase sales by offering low prices to pharmacies. See id.; CVS Cpt. at ¶16. It would also be socially undesirable for generic companies to exploit the market defect by detailing to doctors: when two companies market chemically identical drugs to doctors, they are both able to exploit the defect and sell their products at supracompetitve prices. See CVS Cpt. at ¶13.

1. The Economic Rationale For Generic Substitution Laws

Today, all 50 states have Drug Product Selection ("DPS") laws that permit or require the pharmacist to dispense a generic drug in lieu of a brand drug whenever possible. CVS Cpt. at ¶16. These DPS laws *are premised on the economic fact that brand companies exploit the market defect by promoting to doctors and that generic companies are unable to do so and therefore promote their products by offering low prices to pharmacies:*

> Since physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on others who have both the power and the incentive to respond to lower prices.

[5] See also FTC Staff Rep. at 35-36 (heavy detailing reinforces "doctors' brand-name prescribing habits," extends brand dominance "long after patents have expired," and "reduces the degree of substitutability between products" allowing higher prices).

> *That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists. Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition with other pharmacies on prescription prices.*

Generic Substitution at 7 (emphasis added).

DPS laws "shift the choice of [drug product] for most prescriptions from the physician to the pharmacist." Id. As the FTC put it, "the laws foster price competition by allowing the only principals who have financial incentives to make price comparisons – the pharmacist and the patient – to select drug products on the basis of price." FTC Staff Rep. at 7; see also CVS Cpt. at ¶16.

2. State And Federal Promotion of Generic Entry

Based on this economic rationale, it became State and national policy to encourage generic substitution for branded drugs. Working together, the FTC and the FDA in 1979 developed a Model Drug Product Selection Act ("Model Act") for State legislatures to enact. See FTC Staff Rep. at 273. The Model Act permits pharmacists to dispense an AB-rated generic unless the doctor specifies that the brand is medically necessary. The FTC and FDA were "committed to facilitating drug product selection [i.e., generic substitution]," and believed "that effective drug product selection laws will work to stimulate price competition in a multi-source prescription drug market." Id. at 291.

The FDA also helped promote generic substitution by developing a list of therapeutically equivalent, AB-rated drugs that could be safely substituted for branded products (today called the "Orange Book"). The purpose of the FDA's list was to "enhance the ability of drug purchasers to recognize and take advantage of opportunities for direct savings by drug selection." Rules and Regulations, Dept. of Health and Human Services, Food and Drug Admin., Therapeutically Equivalent Drugs; Availability of List, 45 F.R. 72582 (Oct. 31, 1980) at 41. This list helps make

drug products "sufficiently interchangeable so that price can be a major factor in their selection." Office of Technology Assessment, Drug Bioequivalents, at 57 (July 1974).

These (and other) federal administrative efforts to encourage generic substitution were ratified by Congress in 1984 with the enactment of the Hatch-Waxman Act. As noted in detail above, that Act speeded generic entry by easing the FDA approval process.

C. Defendants' Wrongful Scheme

In 1998, Defendants entered the fenofibrate market with TriCor in a 67 mg capsule form, and, in 1999, with a 134mg and 200mg capsule (hereinafter "TriCor 1"). Defendants quickly garnered substantial revenues from the sale of TriCor capsules, generating over $277 million in revenues in 2001. DPC Cpt. at ¶46. They knew, however, that their blockbuster product suffered from a critical weakness: the lack of patent protection over the fenofibrate compound. Without the "exclusivity" granted by such a compound patent, they knew that TriCor faced a substantial threat from the market entry of generic versions of TriCor 1. See CVS Cpt. at ¶ 18; Walg. Cpt. at ¶ 21; DPC Cpt. at ¶ 2.

In anticipation of the competitive threat posed by generics, Defendants developed a multifaceted plan – euphemistically called REDACTED strategy – to maintain their monopoly power in the fenofibrate market for years by improperly preventing generic companies from effectively competing with TriCor. This strategy involved: (a) developing new forms which would be bioequivalent, but not AB-rated to, the prior form; (b) filing sham patent suits to delay generic entry; (c) forcibly converting the market demand for fenofibrate to the new form before generic versions of the prior form could hit the market; and (d) destroying the market for the prior

form so that it could not compete with the new form. The first market conversion provides a clear example of the exclusionary nature of the scheme.

1. The First Conversion

On November 10, 1999, just 18 months after introducing TriCor 1, Defendants applied for FDA approval to market a tablet version of TriCor, in 54mg and 160mg strengths ("TriCor 2"). Notably, TriCor 2 offered no benefits of any kind to consumers, as compared to TriCor 1. See CVS Cpt. at ¶ 50; Walg. Cpt. at ¶ 51; DPC Cpt. at ¶¶ 79–80. Indeed, Defendants purposefully established, and the FDA found, that TriCor 2 was bioequivalent to TriCor 1. Importantly, however, Defendants designed TriCor 2 so that it had a different dosage form (tablet) and different dosage strengths (54 mg and 60 mg) than TriCor 1 (capsules at 67, 134 and 200 mg). The purpose and effect of these changes – which provided no benefits of any kind to consumers – was to impede generic competition by ensuring that generic versions of TriCor 1 would not be AB-rated to (and thus would not be substitutable for) TriCor 2. See id.

Defendants knew that they would need to buy time to shift demand from TriCor 1 to TriCor 2, before generic versions of TriCor 1 were launched. Timing was critical because, as Defendants knew, once AB-rated generic versions of TriCor 1 entered the market, most prescriptions written for TriCor 1 could be – and would be – filled with the generic. But, if Defendants were able to shift demand to TriCor 2 before generic versions of TriCor 1 reached the market, then prescriptions written for TriCor 2 could not be filled with a generic version of TriCor 1 because the generic would

not be AB-rated to TriCor 2. See CVS Cpt. at ¶¶ 51–54; Walg. Cpt. at ¶¶ 53–55; DPC Cpt. at ¶¶ 80–83. A prompt conversion, then, would effectively protect Defendants' TriCor monopoly.[6]

(a). The Sham Capsule Litigation

In 2000 and 2001 Defendants brought sham patent suits in the Illinois District Court against generics Teva and Impax, after those companies filed ANDAs seeking FDA approval to market generic TriCor 1 (the "Capsule Litigation"). See CVS Cpt. at ¶¶ 41–47; Walg. Cpt. at ¶¶ 42–48; DPC Cpt. at ¶¶ 62–77. Defendants knew that they had no objective basis to claim that Teva's and Impax's generic capsules infringed the '726 patent. They nevertheless filed the suits in order to get the automatic Hatch-Waxman 30-month stay.[7] See infra at pp. 34-41

Although Defendants predictably lost the Capsule Litigation, those lawsuits, as intended, helped provide Defendants with the necessary time to force the market conversion from TriCor 1 to TriCor 2 before the FDA could approve generic TriCor 1.

(b). The Conversion of Fenofibrate Demand From TriCor 1 To TriCor 2

As part of their exclusionary scheme, Defendants engaged in numerous interrelated acts in order to maximize the exclusionary effect of their introduction of new bioequivalent, but not AB-rated, forms of TriCor. First, promptly after obtaining FDA approval for TriCor 2, Defendants stopped all new sales of TriCor 1, and directed their sales force to sell only TriCor 2 in the future, and to pressure doctors not to write prescriptions for TriCor 1. See CVS Cpt. at ¶¶ 51–52; Walg.

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[7] The reasons why the '726 suits were objectively and subjectively baseless are detailed in DPC Cpt. at ¶¶ 80–91. See also pp. 34-41 below (addressing Plaintiffs' sham litigation allegations).

Cpt. at ¶¶ 52–53; DPC Cpt. at ¶¶ 81–82. Through this tactic, Defendants intended that, by the time that generic capsules hit the marketplace, all doctors would be writing prescriptions only for TriCor 2, instead of TriCor 1. Since generic TriCor 1 would not be readily substitutable for TriCor 2, Defendants' conversion of the market to TriCor 2 before generic entry eliminated the possibility that generic capsules could efficiently and effectively enter the fenofibrate market. Meanwhile, Defendants ceased selling TriCor 1, knowing that most retail pharmacies would use up their supply within 30-60 days. As a result of Defendants' "draining" TriCor 1 from the distribution channel, there was little or no TriCor 1 available in the market by mid-April 2002 when Teva entered the market with a fenofibrate capsule product. Thus, most prescriptions written for TriCor 1 before Teva's entry likely would have already been switched by physicians to the TriCor 2 tablets by the time Teva entered the market with its generic version of TriCor 1 capsules. See CVS Cpt. at ¶¶ 53–55; Walg. Cpt. at ¶¶ 52–56; DPC Cpt. at ¶¶ 83–84.

Second, Defendants took other steps to destroy any demand for TriCor 1 that might have continued to exist despite their sales tactics. For example, Defendants caused First Data Bank to list as "obsolete" the TriCor 1 product code in the NDDF, a database used in the industry to determine when an AB-rated generic may be freely substituted for a brand. Under a policy which Defendants knew was followed by First Data Bank, if a company pulled a product from the market and designated a brand name drug as "obsolete" in the NDDF, the NDDF would identify AB-rated generic versions of that drug as branded versions. This impedes generic substitution for that product because third party plans charge consumers higher prices for "brand" drugs than for "generic" drugs. Defendants knew their manipulation of the NDDF would further impede Teva's and Impax's ability to compete. See CVS Cpt. at ¶¶ 56–57; Walg. Cpt. at ¶¶ 57–61; DPC Cpt. at ¶¶ 85–86

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Third, Defendants hastened the conversion from TriCor 1 to TriCor 2 by creating the false appearance that TriCor 2 was superior because the FDA had approved a new indication to TriCor 2 for raising HDL (good cholesterol). Defendants did not disclose – to doctors, third-party payors or consumers – that the very same "raising-HDL" benefit of TriCor 2 was equally obtainable from TriCor 1. Indeed (a) the very data used to obtain this raising-HDL indication for TriCor 2 was derived from Defendants' scientific testing used to support their TriCor 1 NDA; and (b) Defendants intentionally declined to seek FDA approval for the raising-HDL indication for TriCor 1 so that they later could use that indication to falsely market TriCor 2 as improved. See CVS Cpt. at ¶¶ 59–61; Walg. Cpt. at ¶¶ 63–66; DPC Cpt. at ¶¶ 87–88.

Through these interrelated tactics, Defendants succeeded in almost completely shifting the demand for fenofibrate from TriCor 1 to TriCor 2 before April 2002, when Teva's generic TriCor 1 came to market, preventing Teva (and other companies) from effectively competing with Defendants. See CVS Cpt. at ¶¶ 64–65; Walg. Cpt. at ¶¶ 68–69; DPC Cpt. at ¶¶ 92–95

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2. *The Second Conversion*

Defendants knew that there was no valid patent protecting the fenofibrate molecule. Their monopolistic scheme therefore demanded a continuing series of conversions, because the Hatch-Waxman Act would encourage Teva and Impax (among others) to develop AB-rated generic

versions of TriCor 2. Thus, even while the first conversion was in progress, Defendants were working on a second tablet formulation, which became TriCor 3. As with the first tablet, Defendants intentionally formulated TriCor 3 in different dosages/strengths so it would not be AB-rated to its predecessor (TriCor 2), ensuring that Defendants could convert demand from TriCor 2 to TriCor 3 before generic versions of TriCor 2 could enter the market. The only arguable improvement over TriCor 1 or TriCor 2 was the inclusion of technology licensed by Defendants from Elan that allows the product to be taken other than at meals. That license is exclusive and, as shown in detail below (infra at pp. 33-34), is unlawful. In any event, any consumer benefits provided by that technology are far outweighed by the anticompetitive impact of the conversion scheme and by the increased cost of the new branded product relative to the excluded generics. See DPC Cpt. at ¶¶108-09.

As with the first conversion, Defendants filed a series of baseless lawsuits in order to buy time to complete the second conversion. Upon receiving notice of Teva's and Impax's applications to market generic versions of TriCor 2, Defendants again reflexively filed another round of patent infringement suits, this time before this Court, without regard to whether those suits had any merit. These suits were based on patents which Defendants obtained during the additional period of market dominance that the first conversion had afforded them, and triggered multiple 30-month stays of approval of Teva's and Impax's proposed generic tablets. See CVS Cpt. at ¶¶ 66–71; Walg. Cpt. at ¶¶ 71–77; DPC Cpt. at ¶¶ 97–102. After having again successfully carried out a conversion from an existing form which faced imminent generic competition to a new form, Defendants again poisoned the marketplace for generic rivals by draining TriCor 2 from the distribution channel before the generics could enter. See CVS Cpt. at ¶¶ 103–07; Walg. Cpt. at ¶¶ 110–15; DPC Cpt. at ¶¶ 104–17.

3. The Anticompetitive Intent and Effect of Defendants' Scheme

The purpose and effect of the conversion strategy was, from beginning to end, to protect Defendants' fenofibrate monopoly from generic competition. See CVS Cpt. at ¶¶ 108–11; Walg. Cpt. at ¶¶ 116–19; DPC Cpt. at ¶¶ 155–58.

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If Defendants had been interested in introducing a superior new TriCor product, they could have done so without affirmatively taking steps to destroy the market for the prior form. That Defendants took such steps reflects that their goal, as clearly shown in their own internal documents, was not to improve their product or reduce its cost, but to stymie generic competition and preserve their monopoly power. See CVS Cpt. at ¶¶ 64, 107; Walg. Cpt. at ¶¶ 68, 116; DPC Cpt. at ¶¶ 91–93, 114 –117. That their ongoing scheme has successfully stymied competition from generic fenofibrate is reflected in the fact that, despite the generic companies' efforts to seek and obtain FDA approval for generic versions of fenofibrate, as of 2004, Defendants maintained control of 95% of the

fenofibrate sales in the United States, receiving over $750 million in revenues in 2004 alone. See DPC Cpt. at ¶10.

III. ARGUMENT

A. Standard of Review

A court considering a motion to dismiss "must accept as true all factual allegations in the complaint and draw all reasonable inferences in the light most favorable to the plaintiff. Only if it is certain that no relief could be granted under the facts pleaded" is dismissal permitted. Bowley v. City of Uniontown Police Dept., 404 F.3d 783, 786 (3d Cir. 2005). On such a motion, "the issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 235-36 (1974). Furthermore, a court may consider "document[s] integral to or explicitly relied upon in the complaint" without converting a motion to dismiss into a motion for summary judgment. In Re Rockefeller Center Prop., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir. 1999).

The elements of a Section 2 claim are: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident." U.S. v. Grinnell, 384 U.S. 563, 570-71 (1966).[8] Here, Defendants' motion does not challenge Plaintiffs' allegations that Defendants possessed monopoly power, which is defined as "the power to control prices or exclude competition." United States v. E.I. duPont de Nemours & Co., 351 U.S. 377, 391

[8] While Plaintiffs also asserted conspiracy claims under Section 1 of the Sherman Act, with only one exception, Defendants' arguments were addressed to Plaintiffs' Section 2 claims. That lone exception is address infra, at section III.L.

(1956). The only issue, then, is whether Plaintiffs have alleged facts sufficient to show that Defendants willfully acquired or maintained that power.

The standard for determining whether conduct is unlawfully exclusionary under Section 2 is well-settled: "If a firm has been 'attempting to exclude rivals on some basis other than efficiency,' it is fair to characterize its behavior as predatory." Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605 (1985) (citation omitted). Unlawful conduct by a monopolist includes behavior that "not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." Id. at 604 n.32 (quoting 3 P. Areeda & D. Turner, Antitrust Law 78 (1978)); see also LePage's, 324 F.3d at 147 (exclusionary practice is competition "on some basis other than the merits").

Applying this standard, the Third Circuit has held that **"behavior that otherwise might comply with the antitrust law may be impermissibly exclusionary when practiced by a monopolist."** Dentsply, 399 F.3d at 187 (emphasis added); LePage's, 324 F.3d at 151-52 ("monopolist is not free to take certain actions that a company in a competitive . . . market may take"). As many courts have noted, "anticompetitive conduct can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." Conwood v. U.S.T.C., 290 F.3d 768, 788 (6th Cir. 2002) (quotation omitted). The Supreme Court has therefore "preferred to resolve antitrust claims on a case-by-case basis, focusing on the 'particular facts disclosed by the record.'" Eastman Kodak Co. v. Image Tech. Serv., Inc., 504 U.S. 451, 457 (1992) (citations omitted). Determining whether a monopolist's conduct is anticompetitive is inherently fact-intensive and context-dependent, and therefore, "only a thorough analysis of each fact situation will reveal whether the monopolist's conduct is unreasonably anti-

competitive and thus unlawful." Conwood, 290 F.3d at 782.

In analyzing any conduct by a monopolist, efficiency is the touchstone. Of critical importance here, a monopolist's conduct is unlawfully exclusionary when its primary purpose and effect is to impair the ability of rivals to compete. See, e.g., Dentsply, 399 F.3d at 195 (practice unlawful when monopolist "raise[d] its [rivals] costs"); In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 397 (3d Cir. 2000) (antitrust injury where effect of brand manufacturer's conduct "was to raise Barr Laboratories' cost to enter the [generic] market and to disable its market penetration"); Forsyth v. Humana, 114 F.3d 1467, 1478 (9th Cir. 1997) (hospital's policy of referring indigent patients to rivals is unlawful if it "increased the operating cost of those competitors"). See generally T. Krattenmaker and S. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price,* 96 Yale. L.J. 209 (1986).

Direct Purchaser Plaintiffs here have alleged a whole series of interrelated exclusionary acts, including: (a) filing baseless lawsuits in order to take advantage of the Hatch-Waxman Act's 30-month stay; (b) using that period of delay to develop a new form of TriCor that provided no new benefits of any kind to consumers, but was designed to be non-AB rated to, and not substitutable for, generic versions of the existing TriCor; (c) misrepresenting the new TriCor 2 form as "improved" over TriCor 1 when in fact it was not; (d) draining supplies of the older version from the distribution channel to force patients to switch to the new form before generic versions of the older form could enter the market; (e) listing the older TriCor form as "obsolete" in the NDDF to impede and discourage generic substitution; and (f) entering into an unlawful exclusive license. See § III. C-G.

As Plaintiffs show in detail below, each of these acts is unlawfully exclusionary in and of itself, but Plaintiffs have also alleged that each of the acts is part of an overarching scheme that is

also unlawful. Considered both individually and collectively, Defendants' conduct as alleged by Plaintiffs is clearly exclusionary under well-settled law.

B. Defendants' Design Changes Are Exclusionary.

The fundamental premise of Defendants' motion with respect to the design changes – i.e., the intentional changes in order to make the new forms non-AB rated to the prior forms – is that Plaintiffs' complaints admit that the design changes were "improvements." Dfts Bf at 8, 12. As Plaintiffs demonstrated in detail above, this premise is false. The allegations that Plaintiffs have actually made – not those that Defendants wish we had made – satisfy each potentially applicable legal standard for analyzing product design changes – including Defendants' proposed standard.

1. Plaintiffs Have Alleged That The Design Changes Were Not Improvements.

TriCor 2 tablets were no improvement over the bioequivalent TriCor 1 capsules. The three features that Defendants claim are "improvements" are that: 1) tablets are better than capsules; 2) the tablets have a lower dosage of active ingredient; and 3) the tablets were approved for an indication that the capsules were not approved for, i.e. raising HDL. The first two are simply differences, without significant distinction. The third is simply sleight of hand.

(a). Change from Capsule to Tablet

The Complaints allege that the capsule to tablet change "offered no benefits of any kind to consumers," and that allegation must be accepted as true for purposes of this motion. CVS Cpt. at ¶ 50. Defendants vaguely suggest that somehow tablets are superior to capsules (Dfts Bf at 12), but that simply contradicts Plaintiffs' allegation. Indeed, Plaintiffs allege that when another Abbott product (Hytrin) was facing imminent generic competition, Abbott switched from a tablet (to a

capsule). See DPC Cpt. at ¶ 116.[9] The relative superiority of tablets or capsules presents a factual dispute and Plaintiffs' allegations, not Defendants' denials, must be accepted as true on this motion.

(b). Lower Dosage

Defendants assert that the tablets permit a lower dosage to be taken with the same effect as the capsules, but this does not establish an improvement. See Dfts Bf at 12. Instead, Defendants got FDA approval for the lower-dosage tablets by using the same studies submitted to get approval for the higher-dosage capsules and by proving to the FDA that the capsule and tablet dosages were bioequivalent and had the same biovailability. See CVS Cpt. at ¶58; Walg. Cpt. at ¶ 62; DPC Cpt. at ¶¶ 87. Defendants' suggestion that TriCor 2 had "improved bioavailability" (Dfts Bf at12) simply contradicts Plaintiffs' allegations, not to mention the FDA's own conclusion, that TriCor 2 had the same bioavailability as TriCor 1.

(c). Raising HDL Indication

Finally, Defendants assert that TriCor 2 had an "improved feature" because it was approved by the FDA for raising HDL. But Plaintiffs allege that TriCor 1 in fact raises HDL in exactly the same manner as the tablets. Indeed, the data that Defendants submitted to gain supplemental FDA approval for other indications for TriCor 1 included the data that Defendants later used to gain approval for the HDL indication for TriCor 2. See CVS Cpt. at ¶¶ 58–60; Walg. Cpt. at ¶¶ 62–63; DPC Cpt. at ¶ 87. As part of their anticompetitive scheme, however, Defendants affirmatively did not seek an FDA-approved HDL indication for TriCor 1, instead waiting to obtain that approval only

[9] Not coincidentally, at the time Abbott converted Hytrin from tablets to capsules, Hytrin faced imminent competition from generic tablets. Here, also not coincidentally, Abbott converted TriCor in the opposite direction—from capsules to tablets—because it faced imminent competition from generic capsules.

for TriCor 2. See CVS Cpt. at ¶60; Walg. Cpt. at ¶ 64; DPC Cpt. at ¶ 88. That conduct was itself unlawful. See infra at § III.B. The antitrust law is concerned with real improvement, not sham improvement consisting of intentionally withholding an attribute from product A so that the monopolist can later include it in product B and assert an improvement.

2. *Defendants' Design Changes Were Unlawfully Exclusionary Under Each Potential Test.*

Defendants' design changes are unlawfully exclusionary under both of the tests that courts have applied, *i.e.* the Rule of Reason test and the "Profit Sacrifice" test. Defendants advocate a different test, based on snippets of an outdated section of the Areeda-Hovenkamp treatise. Defendants' design changes are unlawfully exclusionary under even that test.[10]

a. **Defendants' Design Changes Are Unlawfully Exclusionary Under the Rule of Reason.**

The Rule of Reason is the appropriate standard in most section 2 cases, including this case. See, e.g., Standard Oil Co. v. United States, 221 U.S. 1, 61-62 (1911); Kodak, 504 U.S. at 478-79; Aspen Skiing, 472 U.S. at 605, 608. The Third Circuit recently applied a rule of reason analysis in LePage's and Denstply. In LePage's, after finding that 3M's discount bundling contracts had an

[10] Contrary to Defendants' implication, there is no presumption of legality for a monopolist's design changes. Courts appropriately exercise caution when considering antitrust challenges to a monopolist's product design changes, but "Judicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful." Microsoft Corp., 253 F.3d at 65; see also Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 n.30 (2d Cir. 1979) ("This is not to say, of course, that new product introductions are ipso facto immune from antitrust scrutiny..."); Northeastern Tel. Co. v. AT&T, 651 F.2d 76 (2d Cir. 1981) (remanding Section 2 claim for trial where the sole remaining allegation of anticompetitive conduct was the design change); Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 545 (9th Cir. 1983) ("We do not, of course, hold that product innovation is immune from antitrust scrutiny and may never provide the requisite conduct element in support of a claim for monopolization or attempted monopolization under section 2 of the Sherman Act.").

anticompetitive effect, the Court found that 3M's proffered procompetitive justification lacked support in the evidence. 324 F.3d at 164. In Dentsply, after finding the exclusive dealing practices to be anticompetitive, the Court found Dentsply's pro-competitive justification was pretextual and did not enhance efficiency or service to customers. 399 F.3d at 196-97.

Other courts have applied the Rule of Reason to allegations of exclusionary product design changes. For example, in United States v. Microsoft, 253 F.3d 34 (D.C. Cir. 2001) (en banc), a case ignored in Defendants' brief, the Court found that changes had the effect of favoring Microsoft's Internet browser, making it difficult for consumers to choose a rival browser product. The Court held that the changes helped maintain Microsoft's monopoly over the operating system and, without any procompetitive justification, violated Section 2. Id. at 67. Other courts have also applied the Rule of Reason to determine the legality of design changes. See, e.g., Multistate Legal Studies, Inc. v. Harcourt Brace Jov. Legal & Prof'l Publ., Inc., 63 F.3d 1540, 1551 (10th Cir. 1995); Caldera Inc. v. Microsoft Corp., 72 F. Supp. 1295, 1313 (D. Utah 1999).[11]

Plaintiffs have clearly alleged facts here which, if taken as true (as the Court must on this motion), establish that Defendants' design changes were unlawful under the Rule of Reason. As shown above, the purpose and effect of the conversion from TriCor capsules to tablets was to impede competition from generic capsules. The higher price of the tablets over the generic capsules, and the coercion of and elimination of consumer choice between the generic capsules and the tablets,

[11] Courts apply the following framework under the Rule of Reason: (1) plaintiff must show that the challenged conduct had an anticompetitive effect; (2) then the monopolist may proffer a procompetitive justification for its conduct, demonstrating that its conduct is a form of competition on the merits because it involves, for example, greater efficiency; (3) if the plaintiff rebuts the claim of procompetitive justification, the plaintiff wins; and (4) if the monopolist succeeds on its assertion of a procompetitive justification, then the plaintiff must show that the anticompetitive harm (continued...)

are classic harms under Section 2. See Eastman Kodak, 504 U.S. at 478 (exclusionary conduct resulting in higher prices "is facially anticompetitive and exactly the type of harm that the antitrust laws aim to prevent"); In re Warfarin, 214 F.3d at 401 ("It is difficult to imagine a more formidable demonstration of an antitrust injury" than allegations of overcharges caused by conduct which impeded generic competition); Dentsply, 399 F.3d at 190 (limiting consumer choice is anticompetitive). As a result of Defendants' conduct, generic competitors were precluded from efficiently entering the market and consumers were robbed of the ability to choose, forcing them to pay over one billion dollars more for fenofibrate than they would have paid absent this scheme. See, e.g., CVS Cpt. at ¶17. Moreover, Plaintiffs have alleged that the capsule to tablet switch offered no improvement to consumers, so there is nothing to balance against the anticompetitive effect. Thus, the Complaints clearly state a claim under the Rule of Reason.

b. Defendants' Design Changes Were Unlawfully Exclusionary Under The Profit Sacrifice Test

Another way for courts to determine whether conduct is exclusionary under Section 2 is to apply a "Profit Sacrifice" test, which considers whether it would have made economic sense for the monopolist to engage in the challenged action if the conduct did not have the effect of excluding competition. See, e.g., Neumann v. Reinf. Earth Co., 786 F.2d 424, 427 (D.C. Cir. 1986). The test asks if Defendants would have anticipated that conduct would be "profit maximizing except for the expectation that (1) actual rivals will be driven from the market, or the entry of potential rivals blocked or delayed, so that the predator will gain or retain a market share sufficient to command

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outweighs the alleged procompetitive benefits. Microsoft, 253 F.3d at 58-59.

monopoly profits, or (2) rivals will be chastened sufficiently to abandon competitive behavior the predator finds threatening to its realization of monopoly profits." Id.; see also Verizon Comm. Inc. v. Trinko, 124 S. Ct. 872, 880 (2004) ("The unilateral termination of a voluntary (and thus presumably profitable) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end"); Spirit Air., Inc. v. Northwest Air., Inc., 2005 WL 2990632 (6th Cir. 2005) (profit sacrifice test may show that increase in capacity was exclusionary); Advanced Health-Care Services, Inc. v. Radford Comm. Hosp., 910 F.2d 139, 148 (4th Cir. 1990) (conduct is exclusionary if monopolist made "a short term sacrifice in order to further its exclusive, anticompetitive objective").[12] The Profit Sacrifice test is well-suited to apply to product design changes. See C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1382 (Fed. Cir. 1998) (plaintiff "was required to prove that Bard made a change in its Biopty gun for predatory reasons, i.e. for the purpose of injuring competition in the replacement needle market, rather than for improving the operation of the gun").

Plaintiffs specifically allege that Defendants' product conversion from the capsules to the tablets fails the Profit Sacrifice test. See CVS Cpt. at ¶63; DPC Cpt. at ¶¶89-92.[13] The detailed

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[12] See also Gen. Indus. Corp. v. Hartz Mount. Corp., 810 F.2d 795, 804 (8th Cir. 1987) (exclusionary conduct is "conduct without a legitimate business purpose that makes sense only because it eliminates competition"); J. Ordover and R. Willig, *An Economic Definition of Predation: Price and Product Innovation*, 91 Yale L.J. 8 (1981) ("Predatory behavior is a response to a rival that sacrifices part of the profit that could be earned under competitive circumstances, were the rival to remain viable, in order to induce exit and gain consequent additional monopoly profit").

[13] A showing that Defendants' conduct fails the Profit Sacrifice test is sufficient to prove that the conduct is exclusionary, but it is not necessary. All conduct that flunks the Profit Sacrifice test is exclusionary, but not all conduct that is exclusionary flunks the Profit Sacrifice test. Indeed, some conduct that is highly effective in excluding competitors and that has no social value – including

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allegations fully support this contention. In switching from capsules to bioequivalent tablets, Defendants undertook significant effort and expense and forsook short-term profits, which made no economic sense but for the exclusionary effect of eliminating competition from generic capsules. Defendants had to invest significant resources in developing and marketing a tablet version of the capsule, including research to determine the appropriate dosage to ensure bioequivalency; changes to the manufacturing process; enhanced marketing to convince doctors to prescribe the tablets instead of the capsules; and losses from returned goods and lost business as a result of draining the distribution channel. Id. Defendants incurred all of these expenses, but knew that the result would be the marketing of a product that was in all relevant respects equivalent to their capsule product.[14] The design changes were profitable only because they had the effect of impairing rivals – a classic indication of exclusionary conduct.

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some of the conduct alleged here – is essentially costless. See Creighton, et al, *Cheap Exclusion*, 72 Antitrust L.J. 975, 979-80 (2005).

[14] Plaintiffs' allegations that the design changes flunked the Profit Sacrifice test also dispose of three themes that Defendants weave throughout their brief. First, Plaintiffs are not proposing a post hoc examination of Defendants' conduct. Contra Dfts Bf at 13. The Profit Sacrifice test is applied ex ante, and evaluates whether Defendants expected to earn additional revenue. Second, Plaintiffs are not arguing that Defendants must expend resources or take affirmative acts to aid their competitors. Contra Dfts Bf at 14. The essence of the Profit Sacrifice test is that it identifies cases in which Defendants have sacrificed profits in order to hurt rivals. Plaintiffs do not assert that a monopolist must spend money to help competitors; we assert – in conformity with the case law -- only that a monopolist must refrain from spending money to hurt competitors. Third, Plaintiffs do not ask the Court to regulate which products a monopolist must develop. Contra Dfts Bf at 4. The Profit Sacrifice test imposes no affirmative duty, but only a negative duty – to refrain from spending money for the purpose of impairing rivals' efficiency.

c. Defendants' Design Changes Were Unlawfully Exclusionary Even Under Their Own Proposed Test

As shown above, Defendants' design changes are unlawful under the two tests traditionally applied by the courts (the Rule of Reason and Profit Sacrifice tests). So, Defendants ignore those two tests and propose a standard, gleaned from portions of the 2002 version of the Areeda-Hovenkamp treatise, that would require a showing that Defendants knew "before introducing the improvement into the market that it was absolutely no better than the prior version, and that the only purpose of the innovation was to eliminate the complementary product of a rival." Dfts Bf at 10, quoting IIIA Areeda & Hovenkamp ¶ 776d (2002).

The Court need not wrestle now with whether the Hovenkamp test, cited by Defendants, could be justified because Plaintiffs' allegations satisfy even this test. Plaintiffs allege not only that the change to TriCor 2 "offered no benefits of any kind to consumers" (CVS Cpt. at ¶50), but also that the change was actually "disadvantageous to patients." Id. at ¶58. Plaintiffs have further alleged that Defendants' only intention in executing the conversion was to injure generic competition. Id. at ¶64. Thus, even under Defendants' view of the law, their motion must be denied.

It bears noting, however, that Professor Hovenkamp has subsequently revised his proposed test. The volume of the Hovenkamp general antitrust treatise cited by Defendants was published in 2002. Professor Hovenkamp has subsequently published a new treatise devoted entirely to the intersection of antitrust and intellectual property law. See Herbert Hovenkamp, et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2005) (hereinafter, Hovenkamp, *IP and Antitrust*).[15]

[15] Relevant portions of this text are included in Direct Purchaser Plaintiffs' Compendium of (continued...)

In a much more detailed and expanded discussion than in the general antitrust treatise, Hovenkamp states that a product design is shielded from antitrust liability only "if a product is a significant improvement over the prior art, and the improvement could not have been accomplished without [impairing competition from rivals]." Id. at § 12.3e at 12-19. He emphasizes that "it is not sufficient to show any improvement; the improvement in question must be 'significant.'" Id. at § 12.3e at 12-19 n.52. When a design change is not shielded from antitrust liability under that standard, Hovenkamp endorses the Rule of Reason analysis employed by the en banc Court in Microsoft. Id. at 12-28. He notes that, "the fundamental inquiry in a Section 2 case (assuming proof of market power) is whether the allegedly anticompetitive practice injures competition unnecessarily." Id. at 12-25.

Hovenkamp emphasizes that "whether an allegedly predatory product change was in fact a genuine innovation is a difficult and fact-specific inquiry." Id. at 12-23. Despite the difficulty of the factual inquiry, courts and juries cannot evade their responsibilities to conduct it:

> In many cases the parties will contest the extent of the innovation or even whether the product was innovative at all. They will also dispute whether the design change was necessary to the innovation; if not, the fact that the new product was innovative as a whole will not justify the design change. Resolving these arguments will require a court to delve into the technical details of the product change. Courts are understandably wary of being caught up in such arguments. But it is an inquiry that must be made in a Section 2 case once market power has been proven.

Id. at 12-26.

Finally, Hovenkamp notes that evidence of the monopolist's intent will help guide the inquiry. Importantly, he provides that, "to require proof that the defendant's intent was solely to

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Unreported Cases and Other Authorities.

disadvantage a competitor would set the burden so high as to make it effectively impossible to meet. Rather, we think proof of a predominant purpose to injure competition should suffice once the remaining standards described in this section have been met." Id. at 12-33 (emphasis in original). Here, Plaintiffs have expressly allege that the design change from TriCor 1 to TriCor 2 was not an improvement at all, and we further alleged that Defendants' intent in implementing the design change was to impair generic competition. See, e.g., DPC Cpt. at ¶¶79-80. Those allegations of fact must be taken as true on this motion, and clearly establish that Defendants' design change was exclusionary under the Hovenkamp test.

C. Defendants' Draining of the Distribution Channel Was Exclusionary.

Defendants withdrew TriCor 1 (and, later, TriCor 2) from the market and then drained the distribution chain of those versions of the product before the generic versions products could reach the market. See CVS Cpt. at ¶¶ 53–55; Walg. Cpt. at ¶¶ 52–56; DPC Cpt. at ¶¶ 83–84. Plaintiffs assert that the draining of TriCor 1 from the distribution channel "had an anticompetitive purpose of effect." CVS Cpt. at ¶53. With respect to TriCor 2, Defendants intensified the draining of the distribution channel by significantly modifying their return-goods policy. Id. ¶ 107. Plaintiffs specifically allege that this conduct fails the Profit Sacrifice test – that it was an investment made by Defendants with the purpose of hindering their competitors. Id.

There is no doubt that such marketing-related conduct can be unlawfully exclusionary. See, e.g., LePage's, 324 F.3d at 153 (monopolist placing its own products in rivals' display racks is "a good illustration of . . . exclusionary conduct"); Multistate Legal Studies, 63 F.3d at 1552-53 (deliberately creating schedule conflicts with rival's services was unlawfully exclusionary); North. Tel. Co. v. AT&T, 651 F.2d 76, 93 n.26 (2d Cir. 1981) ("introduction of a new product may violate

§ 2 if a monopolist acts to compel customer choice by withdrawing a substitute product from the market"). The key here is that Defendants' marketing activity fails the Profit Sacrifice test. For example, in Spirit Airlines (2005 WL 2990632) the Sixth Circuit held that a monopolist airline engaged in exclusionary conduct if its expansion of capacity, aimed at driving a rival from the market, failed the Profit Sacrifice test. Quoting plaintiff's expert, the Court noted, "if the incremental costs of capacity additions . . . are more than the incremental revenues, then the addition of capacity is predatory because it entails losses that can be explained only as an investment to drive [the rival] from the market." Id. at 29. That is exactly what Plaintiffs here have alleged.

Defendants' response that "antitrust laws impose no general duty to aid competitors" (Dfts Bf at 14) is irrelevant. Section 2 of the Sherman Act – especially as reflected in the Profit Sacrifice test – very definitely imposes a duty on monopolists to refrain from spending money for the purpose of harming competitors. Defendants' further assertion that a patent holder has a privilege not to use any of its patented formulations (Dfts Bf at 15) similarly misses the mark, because Defendants did not withdraw any patented technology from the market.

More importantly, Plaintiffs do not allege merely that Defendants withdrew TriCor 1 (and, later, TriCor 2), but that Defendants did so while simultaneously introducing the new TriCor versions and converting the market to them. As both the Supreme Court and the Court of Appeals have repeatedly admonished, Plaintiffs' allegations must be taken in their complete context. Cont'l Ore Co. v. Union Carb. & Carbon Corp., 370 U.S. 690, 698 (1962); LePage's, 324 F.3d at 162. Defendants here would have the Court look at literally only half of the allegation (the withdrawal and draining of the old product) while ignoring the other half (that Defendants did so while introducing a "new" product for the purpose of defeating generic competition). Moreover, with

respect to the draining of the distribution channel, Defendants did not merely refuse to sell the old product – they affirmatively bought back products that they had already sold. See CVS Cpt. at ¶107.

This conduct is not shielded by any "privilege" as asserted by Defendants, and, as alleged by Plaintiffs, the conduct flunks the Profit Sacrifice test. It is plainly exclusionary.

D. Defendants' Manipulation of the NDDF Was Exclusionary

Defendants listed the currently-marketed TriCor formulations as "obsolete" in the National Drug Data File, thereby ensuring that any generic version of that formulation would be more expensive for consumers. CVS Cpt. ¶¶ 56, 106; DPC Cpt. ¶¶ 85, 112. Plaintiffs allege that Defendants listed the products as obsolete "with the purpose and effect of . . . inhibiting generic substitutability for TriCor." CVS Cpt. ¶ 118. This is a classic example of "naked" exclusionary conduct -- conduct that has no socially useful purpose and a clear anticompetitive effect. See, e.g., Allied Tube & Cond. Corp. v. Indian Head, Inc., 486 U.S. 492 (1988) (influencing standard setting organization to adopt standard to inhibit rivals is anticompetitive); In re Buspirone Pat. Litig., 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (improperly listing patent in Orange Book to exclude generics is anticompetitive); Creighton et al., *Cheap Exclusion*, 72 Antitrust L.J. 975 (2005) (discussing numerous examples of such naked exclusionary conduct).

Defendants' only response is that they had a different purpose, i.e., to "notify [] the public" of the discontinuance of the products. (Dfts Bf at 16) Defendants' factual assertion is demonstrably false, as we will prove at trial. For now, it is sufficient to note that Defendants' response contradicts the allegations in Plaintiffs' complaints.

E. Defendants' Misrepresentations Were Exclusionary

Defendants misled doctors and consumers that the "new" TriCor versions offered medical

benefits over the prior versions. See, e.g., DPC Cpt. at ¶88. Misrepresentations as to product attributes can be unlawfully exclusionary under Section 2, particularly when they are a part of a larger anticompetitive scheme. See LePage's, 324 F.3d at 153 ("providing misleading information to retailers" is "a good illustration of . . . exclusionary conduct"); In re Warfarin, 214 F.3d at 397 (claim that generic entry was impaired by "publication and dissemination of false and misleading information to the public" states claim of antitrust injury); Int'l Travel Arran. v. Western Air, Inc., 623 F.2d 1255 (8th Cir. 1980) (deceptive ad campaign must be considered in evaluating claim of anticompetitive scheme). Defendants have not addressed this exclusionary conduct at all, other than by conclusorily asserting that Plaintiffs' factual allegations are wrong.

F. Defendants' Intentional Degrading of TriCor 1 Was Exclusionary

Defendants refused to seek approval for the raising-HDL indication for TriCor 1, even though the clinical studies needed to obtain the indication were readily available to Defendants and in fact had already been submitted to the FDA. CVS Cpt. at ¶ 59. Plaintiffs specifically allege that Defendants intentionally failed and refused to seek the approval for TriCor 1 so that they could later seek it only for TriCor 2, and that they did so "for the purpose of inhibiting generic competition." Id. at ¶60; see also Walg. Cpt. at ¶ 64.

As noted above, Defendants have recognized Professor Hovenkamp as one of the nation's leading authorities on these issues. The Hovenkamp treatise identifies this exact scenario -- a monopolist degrading its own product for the purpose of dampening competition -- as the clearest possible case of an exclusionary product design. Hovenkamp, *IP And Antitrust* § 12.3e.2, at 12-20. Hovenkamp notes that "it is difficult to imagine a plausible competitive reason" for such conduct and that courts have summarily condemned it. Id.; see also North. Tel Co., 651 F.2d at 94 (design of

product to be unnecessarily cumbersome is unlawfully exclusionary); In re IBM Peripheral EDP Devices, 481 F. Supp. 965, 1007-08 (N.D. Cal. 1979) ("the law need not tolerate deliberate acts where the only purpose and effect is to use monopoly power to gain a competitive advantage"), aff'd on other grounds, 698 F.2d 1377, 1382 (9th Cir. 1983). Defendants insist that obtaining an HDL indication is a significant product improvement, and if that is so, their intentional refusal to seek that indication for TriCor 1 is clearly exclusionary.

G. Defendants' Exclusive License With Elan Is Exclusionary

Defendants entered into an exclusive license to obtain some of the patented technology used in TriCor 3. See supra at pp DPC Cpt. at 110-11; Walg. Cpt. ¶ 112 . Defendants attempt to avoid this issue by discussing it only in one sentence in a footnote, and without acknowledging the anticompetitive aspect of the license, i.e., that it was exclusive rather than non-exclusive. See Dfts Bf at 12 n.14. The Hovenkamp treatise pointedly notes that, "acquisitions by a monopolist of exclusive rights in related patents are presumptively a §2 'exclusionary practice.'" Hovenkamp, *IP and Antitrust* § 14.3 at 14-17 (2004 Supp.). The reason for that conclusion is straightforward and fully applicable here: "the acquisition of an exclusive license in a patent covering an improvement to the monopolist's basic patent might enable the monopolist to perpetuate its monopoly beyond the period of the basic patent." Id. at 14-18 (emphasis added); see also Moraine Prod. v. ICI America, Inc., 538 F.2d 134, 145 (7th Cir. 1976) ("where a patent license is used to protect the licensee in addition to the patentee . . . there is good reason to declare such a restrictive scheme illegal"). That is exactly what is happening here – Defendants and Elan are using the exclusive license not to extract the value of the improvement claimed by Elan's patent, but to extract the value of that improvement plus the value of excluding competition on the (unpatented) fenofibrate molecule. The

exclusive license is therefore exclusionary.

H. Defendants' Sham Litigation was Exclusionary

The purpose and effect of Defendants' baseless patent litigation was to maintain and extend the TriCor monopoly, rather than to protect legitimate patent rights. As shown below, the conduct is actionable because it falls within well-recognized exceptions to Noerr-Pennington immunity.[16]

1. The Capsule Litigation Was A Sham

As shown above, Defendants' scheme to impede generic competition included the filing of patent lawsuits against potential generic entrants to obtain the benefit of the Hatch-Waxman 30-month stay — whether or not they had any legal or factual basis to file such suits.

In Prof'l Real Est. Invest., Inc. v. Columbia Pict. Ind., Inc., 508 U.S. 49, 60 (1993) ("PRE"), the Supreme Court established a two-prong test for sham litigation. First, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. Second, "if challenged litigation is objectively meritless [then] . . . a court examine[s] the litigant's subjective motivation." Id.

Here, it is undisputed that Plaintiffs have properly alleged both prongs. First, Plaintiffs allege that no reasonable litigant could have expected success in the Capsule Litigation. Second,

[16] It is also well established that conduct that is part of an overall scheme can be actionable, even if such conduct would be Noerr-protected in isolation. See Alexander v. National Farmers Organization, 687 F.2d 1173,1196 (8th Cir. 1982) ("[e]xempt conduct may be considered . . . to the extent it tends to show the 'purpose or character' of other, nonexempt activity."); Rockbit Industries USA, Inc. v. Baker Huges, Inc., 802 F.Supp. 1544, 1549 (S.D. Tex. 1991) (noting cases which hold that "conduct otherwise immune from the antitrust laws under the Noerr-Pennington doctrine may be attacked if part of an overall scheme to violate the antitrust laws"); ID Security Sys. Can., Inc. v. Checkpoint Sys., Inc., 249 F.Supp.2d 622, 656 n.14 (E.D. Pa. 2003) (the overall scheme creates liability not subject to Noerr-Pennington).

Plaintiffs allege that Defendants' subjective motivation for filing and maintaining the Capsule Litigation was the 30-month stay automatically triggered by the filing of the suits, rather than the outcome of the litigation. See CVS Cpt. at ¶¶ 76–84; Walg. Cpt. at ¶¶ 80–90; DPC Cpt. at ¶¶ 120–25. Thus Defendants' motion, as it relates to Plaintiffs' sham allegations regarding the Capsule Litigation, should be denied outright. [17]

Defendants do not even address Plaintiffs' allegations detailing why the Capsule Litigation was objectively baseless. Instead, they conclusorily argue that: (1) the mere fact that they lost the Capsule Litigation is insufficient to establish a sham; and (2) the Federal Circuit's opinion, affirming that Teva and Impax did not infringe the '726 patent (Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324 (Fed. Cir. 2003)), somehow shows that Defendants' rejected infringement claim was not "so baseless" that it constituted a sham. Dfts Bf at 25.

Defendants' first argument is a strawman. Plaintiffs do not contend that the Capsule Litigation was a sham merely because Defendants ultimately lost; rather, it was sham because, under the facts and law applicable to the suit Defendants never had any reasonable chance to win. See CVS Cpt. at ¶¶ 76–84; Walg. Cpt. at ¶¶ 80–90; DPC Cpt. at ¶¶ 120–25.

Defendants' second argument is similarly specious. Rather than revealing an objective basis for Defendants' infringement claims, the Federal Circuit's unanimous and stinging affirmance of the district court's finding of non-infringement strongly supports Plaintiffs' allegations that no reasonable litigant could have expected the '726 suit to have succeeded on the merits.

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[17] See, e.g., Jarrow Formulas, Inc. v. Int'l Nutrition Co., 175 F. Supp. 2d 296, 310 (D. Conn. 2001) ("[A]ll that is required [to deny a motion to dismiss] is that the complaint allege facts, which, if proven, show that the defendant is not entitled to Noerr-Pennington immunity under the sham litigation exception.") (quoting PRE).

Specifically, the two relevant claims of the '726 Patent require, respectively: (a) "a **co-micronized** mixture of particles of fenofibrate and a **solid surfactant**" and (b) "**co-micronization** of the fenofibrate and a **solid surfactant**." Abbott, 323 F.3d at 1327 (emphasis added). The term "**co-micronization** of fenofibrate and a **solid surfactant**" is explicitly defined in the '726 Patent as "micronization of an intimate mixture of fenofibrate and a solid surfactant." Id. at 1330. The relevant claims of the '726 Patent thus require that a solid surfactant be used, that the fenofibrate and solid surfactant be micronized together as a mixture, and that the fenofibrate/solid surfactant mixture be an intimate mixture.

Teva's ANDA product could not reasonably be viewed as within the scope of the '726 claims because it was made by: (a) micronizing the fenofibrate on its own (rather than co-micronizing the fenofibrate with another ingredient); and then (b) mixing the already-micronized fenofibrate with several other ingredients, including a liquid (rather than solid) surfactant. At no relevant time in Teva's process was the fenofibrate in contact with a solid surfactant. Furthermore, because of the order of mixing, at no time in Teva's process was the fenofibrate in an intimate mixture with any surfactant that excluded the other ingredients. See CVS Cpt. at ¶¶ 76–84; Walg. Cpt. at ¶¶ 80–90; DPC Cpt. at ¶¶ 120–125.

Recognizing this, but desperate to invoke the automatic 30-month stay triggered merely by filing an infringement suit against Teva, Defendants concocted a claim construction position wholly at odds with the plain language of the '726 patent and its prosecution history. Id. Specifically, Defendants asserted that, despite the definition they supplied in the '726 patent, "co-micronized" should be construed broadly to mean "micronized with or together" – thereby allowing for the presence of other components during co-micronization. Abbott, 323 F.3d at 1330.

The Federal Circuit emphatically rejected Defendants' assertion, holding that it was "abundantly clear" that the '726 patent claims require the micronization of a mixture consisting only of fenofibrate and solid surfactant, and do not encompass the micronization of fenofibrate alone or as part of a mixture including other ingredients. Id. (emphasis added). Regarding literal infringement, the Court held that "[b]ecause it is undisputed that fenofibrate and a solid surfactant are not mixed in [Teva's] process without other significant ingredients, *viz.*, excipients and water, being present, we conclude that there is no genuine issue of material fact as to literal infringement in this case," reflecting that no reasonable juror could conclude otherwise. Id., DPC Cpt. at ¶ 74.

Similarly, the Federal Circuit easily rejected, as a matter of law, Defendants' claim of infringement under the doctrine of equivalents, holding that: (1) "there can be no dispute that fenofibrate and solid surfactant are not 'co-micronized' as that term is used in the '726 patent"; and (2) Teva's process "cannot, as a matter of law," constitute co-micronization of fenofibrate with a solid surfactant, since Teva's surfactant "is clearly not a 'solid surfactant.'" Id. at 1331.

Given the Federal Circuit's unequivocal rejection of Defendants' arguments as a matter of law, it is hard to imagine how Defendants can rely on that opinion to refute Plaintiffs' allegations of sham litigation. Since Defendants do not explain how that opinion establishes that the '726 suit was not a sham– and since the opinion clearly supports Plaintiffs' sham claim– Defendants' argument that Plaintiffs have not sufficiently pled that the '726 suit was sham litigation must be rejected.[18]

[18] Defendants' reliance on Teva's and Impax's failure to assert sham litigation claims here regarding the '726 patent is similarly misplaced. As Defendants acknowledge, the assertion of sham litigation was a compulsory counterclaim in the capsule litigation, thus precluding Teva and Impax from asserting that theory in this case. See Dfts Bf at 24 n 21. Moreover, the myriad potential reasons (strategic or otherwise) why Teva and Impax chose not to assert sham claims in the underlying capsule litigation are irrelevant here.

2. *The Tablet Litigation Was A Sham*

Having successfully leveraged the Hatch-Waxman delay from the sham Capsule Litigation to effect the capsule to tablet switch, Defendants embarked on a second round of sham litigation ("the Tablet Litigation") to facilitate a second product switch (and create another hurdle to generic entry) by obtaining additional 30-month stays. Plaintiffs allege that Defendants: (a) sought to enforce patents that were clearly unenforceable because they were obtained through inequitable conduct (the Stamm patents); and (b) improperly opted not to test Teva's tablet product before filing suit on the '726 patent. See CVS Cpt. at ¶¶ 82, 85–102; Walg. Cpt. at ¶¶ 86, 92–109; DPC Cpt. at ¶¶ 126–146.

Defendants do **not** contest that Plaintiffs allege that inequitable conduct occurred during the prosecution of the Stamm Patents, or that such inequitable conduct precluded Defendants from any reasonable chance of success in the Tablet Litigation. See CVS Cpt. at ¶¶ 85–102; Walg. Cpt. at ¶¶ 92–109; DPC Cpt. at ¶¶ 129–46. Nor do Defendants dispute that they filed the Tablet Litigation in 2002 without testing Teva's sample. Instead, Defendants contend that: (a) inequitable conduct cannot, as a matter of law, form the basis of a sham litigation claim under PRE, and (b) testing was unnecessary to provide Defendants with a basis to claim infringement, under Q-Pharma, Inc. v. Andrew Jergens, 360 F.3d 1295 (Fed. Cir. 2004).[19] Dfts Bf at 20.[20] They are wrong on both counts.

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[19] Defendants also argue that "[a]t the end of extensive motion practice, Teva and Impax faced trial on six claims of the '881 Patent and claim 6 of the '405 patent." Dfts Bf at 20. The fact that some claims survived summary judgment does not mean that other claims were not objectively baseless. Defendants cite Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag, 207 F. Supp. 2d 221 (S.D.N.Y. 2002), and two other district court cases for the proposition that a showing sufficient to survive summary judgment is a sufficient indication of probable cause to preclude a conclusion that the litigation was a sham. Dfts Bf at 19-20 & n.18. However, federal appellate courts have taken a different view. FilmTec Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1995) ("[A] preliminary success on the merits does not necessarily preclude a court from concluding that litigation was baseless."); Boulware v. State of Nev., Dep't of Hum. Res., 960 F.2d 793, 798

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Regarding PRE, none of Defendants' cited cases support their proposition that inequitable conduct cannot form the basis for sham litigation under PRE. Three cases predate PRE, and offer no assistance in defining its contours. Defendants' sole post-PRE case, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998), is fatal to Defendants' position. In fact, *Nobelpharma* rejects Defendants' contention that Walker Process and PRE claims are mutually exclusive, instead holding that the Walker Process and PRE doctrines provide "alternative legal grounds" that may be "applied to the same conduct":

> PRE and Walker Process provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws; both legal theories may be applied to the same conduct. Moreover, we need not find a way to merge these decisions. Each provides its own basis for depriving a patent owner of immunity from the antitrust laws; either or both may be applicable to a particular party's conduct in obtaining and enforcing a patent. The Supreme Court saw no need to merge these separate lines of cases and neither do we.

Id. at 1071 (emphasis added). As Nobelpharma makes clear, the same conduct (e.g. misrepresentations to the PTO) may form the basis for a PRE sham litigation claim, even if a Walker Process claim is not (or cannot be) pled based on that conduct, as long as the PRE standards are met

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(9th Cir. 1992) ("[D]efendants urge us to hold that their initial success in the Nevada trial court is determinative of the question whether their state court suit was baseless. We decline to embrace such a per se approach."). Moreover, the fact that Defendants voluntarily dismissed those remaining claims prior to trial but after their product switch was complete is an indication that Defendants were attempting to interfere directly with the business relationships of a competitor through the use of the litigation *process* as opposed to the *outcome* of that process. See PRE, 508 U.S. at 60-61.

[20] Defendants also contend that Plaintiffs have failed to allege antitrust injury because prosecution of the '881 patent litigation did not by itself keep any generic competitors off the market. But, Plaintiffs need not allege that each and every aspect of Defendants' monopolization scheme caused them harm. The requirement of pleading injury under section 4 of the Clayton Act is satisfied by "proof of some damage flowing from the unlawful conspiracy." Zenith Radio Corp. v.

(continued...)

– i.e., where (as here) no reasonable litigant could realistically expect to succeed on the merits of patent litigation because their inequitable conduct clearly rendered the relevant patent unenforceable.

Regarding Q-Pharma, Defendants do not dispute that they filed the Tablet Litigation in 2002 without testing Teva's sample tablet product. Instead, they contend that the Federal Circuit's 2004 decision in Q-Pharma justified their decision. Needless to say, Defendants could not have relied on the 2004 Q-Pharma case when they made their 2002 decision to file suit. Moreover, Q-Pharma makes clear that, at a minimum, Defendants were obliged to "interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement." Id. at 1300-01. In Q-Pharma, the patentee satisfied this requirement by: (a) declaring that, before suit was filed, a claim construction analysis was performed (Id. at 1301), and (b) establishing that a chemical analysis of the accused infringer's product was not necessary **because** a satisfactory infringement analysis was performed using other information– namely, the accused infringer's own advertising and labeling materials (Id. at 1302). Q-Pharma does not suggest that no infringement analysis need be performed. Here, in contrast to Q-Pharma, Defendants performed **neither** a suitable claim construction analysis **nor** a suitable infringement analysis before filing suit, and thus had no reasonable basis to file the suits. See, e.g., DPC Cpt. at ¶126.

I. Defendants' Overall Scheme Was Exclusionary

Defendants do not dispute that Plaintiffs have alleged a scheme that was anticompetitive in both purpose and effect. Rather, Defendants improperly break the alleged comprehensive scheme into individual acts, argue that each separate act was legal or had no anticompetitive effect when

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Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969).

viewed in isolation, and thus erroneously conclude that the scheme cannot be unlawful. As shown above, this argument is inapplicable here because each element of the scheme is independently unlawful. But even if that were not so, Defendants' argument is contrary to well-established Supreme Court and Third Circuit law.

The Third Circuit has clearly recognized that monopolists can violate §2 by engaging in an overall scheme to monopolize. In LePage's, a monopolist engaged in a series of acts, the anticompetitive effect of which became "most apparent when . . . considered as a whole." 324 F.3d at 162. Recognizing this, the Third Circuit, sitting en banc, refused to view each part of defendants' conduct in isolation, but examined the entire course of conduct, holding:

> [t]he relevant inquiry [in monopolization cases] is the anticompetitive effect of [the defendant's] exclusionary practices considered together. As the Supreme Court recognized in Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962), **the courts must look at a monopolist's conduct taken as a whole rather than considering each aspect in isolation.**

Id. (emphasis added).[21] Based on cases like LePage's, several recent cases have specifically upheld the validity of "overall scheme" claims in the Hatch-Waxman context. See, e.g., In re Remeron Antitrust Lit., 335 F. Supp. 2d 528 (D.N.J. 2005) (under LePage's, "the relevant inquiry is the anti-competitive effect of [the defendant's] exclusionary practices considered as a whole"); SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686 (E.D. Pa. 2004) (assessing potentially anticompetitive acts as "part of a larger scheme to maintain the monopoly in the market."); Biovail

[21] See also Caldera, Inc. v. Microsoft Corp., 72 F. Supp. 2d 1295, 1309 (D. Utah 1999) ("[T]o allow defendant to carve plaintiff's complaint into seven discreet claims that plaintiff never intended to allege as independent claims not only appears to offend the purpose behind ' 2, but also turns basic civil procedure principles on their head."); City of Anaheim v. South. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) ("It would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect.").

Corp. Int'l v. Hoechst AG, 49 F.Supp. 2d 750, 759 (D.N.J. 1999) (refusing to address each factual basis for plaintiff's antitrust claims separately).

There is no doubt that a scheme to impede generic entry states a claim of antitrust injury. In In re Warfarin, 214 F.3d at 397, the Court found antitrust injury where the brand manufacturer "orchestrated a campaign disparaging generic substitutes generally, and Barr Laboratories' warfarin sodium particularly." As here, the monopolist, "attempt[ed] to prevent and/or delay [FDA] approval of warfarin sodium in generic form," and the effect "was to raise Barr Laboratories' cost to enter the [generic] market and to disable its market penetration." Id. Where, as here, such a scheme succeeds, "[i]t is difficult to imagine a more formidable demonstration of antitrust injury." Id. at 401.[22]

Defendants' contention that "the alleged scheme hinges on the inclusion of lawful acts and conduct," (Dfts Bf at 29) even if correct—which it is not—does not disturb the Court's analysis of the effect of the overall scheme. It is well-established that a scheme can violate the antitrust laws even if some—or even all—of the elements of that scheme are not independently actionable. See Amer. Tob. Co. v. U.S., 328 U.S. 781, 809 (1946) ("It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful."); Borden, Inc. v. FTC, 674 F.2d 498, 513 (6th Cir. 1982) ("It is not essential to a finding of monopolization ... that acts or

[22] By the same reasoning, this Court should reject the argument that Plaintiffs have failed to plead antitrust injury. Dfts Bf at 29. The Complaints allege that, by decreasing competition in the fenofibrate market, the intent and effect of Defendants' scheme was to impede generic competition, causing Plaintiffs to pay more for fenofibrate than they otherwise would have paid. See, e.g., Walg. Cpt. at ¶127. This is just the type of injury the antitrust laws were intended to prevent and satisfies the requirements of Section 4 of the Clayton Act. See Bruns. Corp. v. Pueblo Bowl., 429 U.S. 477, 489 (1977) (antitrust injury is that which flows from decreased competition); In Re Warfarin, 214 F.3d at 401; Biovail, 49 F. Supp. 2d at 770-71 (plaintiff "need not have been injured by each of the actions which would aid a trier of fact in determining whether defendants were willfully maintaining or attempting to acquire monopoly power in contravention of the Sherman Act").

practices used to maintain monopoly power be in themselves independently unlawful."); Biovail, 49 F.Supp. 2d at 766 ("Defendants' argument that conduct cannot form the basis for an antitrust violation if it is not 'wrongful' for reasons extrinsic to the antitrust laws is simply incorrect."). [23]

The Complaints here allege that, even before TriCor was launched, Defendants knew the significant threat posed by generic rivals, and undertook an overall scheme to extend and protect TriCor's dominance in the fenofibrate market by delaying and impeding generic entry. See supra at pp. 11-17. When evaluated as a whole, Plaintiffs have clearly alleged this scheme was exclusionary and anticompetitive, in violation of §2. And such an exclusionary scheme is illegal, even assuming – contrary to fact – that each act comprising the scheme was lawful if analyzed separately.

J. Proof of a Section 2 Monopolization Claim Requires Only a Showing of Injury to Competition, Not Total Foreclosure of Competition from the Market

Contrary to Defendants' argument, total foreclosure from the market is not required to state a claim under Section 2. See Dfts Bf at 12. The Third Circuit has made clear that "[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply, 399 F.3d at 191. In Dentsply, there were a dozen non-foreclosed competitors in the relevant market, with a combined market share of nearly 25%; despite the fact that there was not total foreclosure, Dentsply was liable under Section 2. Id. at 184. Similarly, in LePage's, the Third Circuit held that a monopolist's bundled rebates can be anticompetitive if they "foreclose portions of the market," (324 F.3d at 155) and Defendant 3M was liable under Section 2 despite the fact that plaintiff LePage's had been on the market over 70 years,

[23] See also Aspen Highlands Skiing Corp. v. Aspen Skiing Co., 738 F.2d 1509, 1522 n.18 (10th Cir. 1984), aff'd, 472 U.S. 585 (1985) (considering record "as a whole" and concluding that it was not necessary for plaintiff to prove that each allegedly anticompetitive act was itself sufficient to (continued...)

and had a market share of 9% during the relevant period. Id. at 162. And in In re Warfarin, the Court found antitrust injury where, exactly as here, "the cumulative effect of [the brand manufacturer's conduct] was to raise Barr Laboratories' cost to enter the [generic] market and to disable its market penetration." 214 F.3d at 397.

Defendants suggest that this Court's decision in Medtronic Minimed, Inc. v. Smiths Medical MD Inc., 371 F. Supp. 2d 578 (D. Del. 2005), requires total foreclosure of competitors. It does not, and, under Denstply, LePage's, and In re Warfarin, it could not. In Medtronic, this Court granted summary judgment (not a motion to dismiss) on an exclusionary tying claim, not because Defendants' acts failed to completely foreclose competitors, but because Defendants' acts did not foreclose competition at all. For example, in Medtronic, the Court noted there were no significant barriers to competitive entry in the relevant market (id. at 587), whereas there are significant barriers to generic entry here (e.g., FDA approval, Hatch-Waxman litigation, Defendants' formulation changes). See CVS Cpt. at ¶¶ 19–33; Walg. Cpt. at ¶¶ 15–34; DPC Cpt. at ¶¶ 31–41. Indeed, in Medtronic, two other competitors had designed around the defendants' patent and entered the market. See 371 F. Supp. 2d at 581. Also, the Medtronic plaintiff did not contend that it was hindered from marketing the new design (id. at 583); did not contend that it had lost any sales as a result of the new design (id. at 584); could have sold compatible products if it chose to do so (id. at 586); and was not "foreclose[d from] the market in any meaningful way." Id. at 587. Here, by contrast, Defendants' anticompetitive conduct foreclosed one generic competitor (Teva) from the vast majority of the fenofibrate market—i.e. its market share was limited to 5%, where absent

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demonstrate an abuse of monopoly power).

anticompetitive conduct, a reasonable expectation would be 80% or more. Likewise, another putative entrant (Impax) viewed entry as futile and stayed out of the market altogether.

Thus, the challenged practices here, unlike those in Medtronic, had a significant anticompetitive effect—an effect which, although less than complete foreclosure, is clearly actionable. See Dentsply, 399 F.3d at 194 ("[t]he paltry penetration in the market by competitors over the years has been a [confirmation of Plaintiffs' theory] by tangible and measurable results in the real world."); LePage's, 324 F.3d at 160 (exclusionary conduct "cut LePage's off from key retail pipelines necessary to permit it to compete profitably"); Microsoft, 253 F.3d at 64 (Microsoft's conduct exclusionary because "although Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones"); CVS Cpt. at ¶65 (Defendants' conduct "excluded [generics] from the most efficient means of distributing their products").

K. Defendants Cannot Offer, and Have Not Offered, a Cognizable Procompetitive Justification

As explained in the Statement of Facts, there were very specific, and often unique, economic underpinnings to Congress' (and the States') enactment of legislation promoting and encouraging generic substitution (i.e., the Hatch-Waxman Act and generic substitution laws). Most importantly, Congress and the States: (1) recognized a serious defect in the pharmaceutical marketplace—the disconnect between the decision makers (doctors) and the payors (consumers and third party payors); and (2) enacted legislation designed to mitigate that defect by encouraging, sometimes even mandating, generic substitution. See Section II.B. above. The States and Congress recognized the inability of generic manufacturers to engage in non-price competition (i.e., marketing) with brand manufacturers, and enacted legislation specifically designed to allow generics – after expiration of the extended exclusivity periods granted to brand manufacturers under Hatch-Waxman – to compete

with such branded manufacturers on price, without requiring generics to do the impossible (*i.e.*, match the brand manufacturers' marketing muscle).

Nonetheless, Defendants essentially assert that impeding successful entry of generic TriCor is not anticompetitive – and, in fact, is procompetitive – because it prevents generic companies from "free riding" on Abbott's detailing to doctors. Dfts Bf at 15. According to Defendants, it would be procompetitive to require generic companies to detail to doctors the way that brand companies do.

First, it is black letter law that the Court should not consider procompetitive justifications on a motion to dismiss. Advanced Health-Care Serv., Inc, 910 F.2d at 145 (on motion to dismiss, court must accept plaintiffs' allegations of adverse effects on competition as true and must consider defendants' pro-competitive justifications as unproven); In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 533 (D.N.J. 2004) (same); Balaco, Inc. v. Upjohn Co., 1992 WL 131150, at *2 (E.D. Pa. 1992) (defendants' position on "pro-competitive effect is not relevant at this stage in the litigation. . . . a factual determination of the actual competitive effects is not appropriate on a motion to dismiss."). Plaintiffs have alleged that there were significant anticompetitive effects, and no procompetitive benefits, from Defendants' scheme to exclude generics, especially since, as explained above, their new forms of TriCor were medically equivalent to the prior forms, but cost significantly more than the excluded generics. To credit Defendants' unproven arguments would require the Court to impermissibly draw inferences that contradict Plaintiffs' allegations and draw inferences in Defendants' favor. See Bowley, 404 F.3d at 786.

Second, even if Defendants' argument were proper on a motion to dismiss (which it is not), it must fail. As shown above, Congress has emphatically promoted the very conduct that Defendants are seeking to impede – prompt generic entry under the Hatch-Waxman regime. Congress' actions

were not taken lightly; they were a thoughtful and carefully balanced response to a serious problem in this country: skyrocketing prescription drug prices. Drug prices are high precisely because doctors are insensitive to price, and brand companies exploit the price disconnect by heavily promoting products to them. The *pro*competitive aspect of generic drugs is that they are not detailed to doctors, but instead are promoted to pharmacies based on price. States enacted, and the federal government supported, DPS laws precisely in order to "shift the choice of [drug product] for most prescriptions from the physician to the pharmacist." Generic Substitution at 1. Defendants cannot avoid liability here by (1) characterizing conduct by generic companies that is encouraged by Congress as anticompetitive "free riding," and (2) characterizing their own conduct, designed to reintroduce the exploitation of market barriers that Congress and the States sought to overcome, as procompetitive.

While Defendants may disagree with Congress' and the States' purpose and intent in enacting Hatch-Waxman and the generic substitution laws, and may even believe such legislation is anticompetitive, they cannot ask this Court to change those laws. This Court must adjudicate whether Defendants' conduct is anticompetitive or procompetitive based on the statutory and regulatory framework under which the challenged conduct occurred -- here, the Hatch-Waxman Act and the generic substitution laws. See Trinko, 124 S.Ct. at 881 ("Antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."). Since those laws are clearly designed to promote price competition by generics – and Defendants' conduct is indisputably designed to have the exact opposite effect – Defendants' procompetitive justifications (i.e., rationalizations) for their plainly exclusionary conduct must fail.

L. Defendants Are Liable for Their Conspiracy to Restrain Trade

Defendants contend that the Complaints are somehow defective because Plaintiffs purportedly did not allege that each Defendant participated in each and every aspect of Defendants' overall scheme. See Dfts Bf at 31. This argument clearly misapprehends both (a) Plaintiffs' allegations regarding Defendants' joint conduct in furtherance of the alleged scheme; and (b) the standards for analyzing antitrust conspiracy claims.

In their brief, Defendants portray themselves as independent actors with perfectly compartmentalized involvement in the alleged misconduct: Fournier was involved only with the development of the various forms of TriCor and the patent-related misconduct; and Abbott alone was responsible for marketing the product. See Dfts Bf at 32, 36. Plaintiffs' allegations, however, tell a different story. As Plaintiffs alleged, Abbott and Fournier: (a) "divided the costs of, and revenues and profits from, TriCor between themselves;" (b) "worked closely and in concert throughout the overarching scheme alleged herein;" and (c) "singularly and jointly, each actively participated in all or most of the components of the exclusionary scheme . . . and each benefited (and continue to benefit) from the scheme." See, e.g., DPC Cpt. at ¶¶162-63, 175-76. Such allegations of joint conduct are clearly sufficient at this early stage of the case.

Moreover, to state a Section 1 conspiracy claim, Plaintiffs need only allege concerted action by two or more persons that unreasonably restrains interstate trade or commerce. See In re Baby Food Antitrust Litig., 166 F.3d 112, 118 (3d Cir.1999). Each member of the conspiracy need not take part in each aspect of the wrongful conduct; all that is needed is an allegation that the conspiracy was undertaken with the wrongful purpose to restrain trade. This "contention that plaintiffs must specifically allege acts committed by each defendant to show its involvement in the

conspiracy is baseless." See In re Vita. Antitrust Litig., 2000 WL 1475705, *11 (D.D.C. May 09, 2000).

Here, Plaintiffs allege that Abbott and Fournier worked closely together, with commonality of purpose and knowledge of each others' actions, to develop and execute the multifaceted scheme alleged herein. Plaintiffs specifically allege in the Complaints–

REDACTED – that these acts were undertaken by Defendants in furtherance of a single scheme with a common goal: to protect the monopoly profits that were the fruit of the scheme (and which profits accrued to both Defendants).[24] Fournier and Abbott are liable for each other's acts in furtherance of their common scheme.[25] See Col. Steel Casting Co., Inc. v. Port. Gen. Elec. Co., 111 F.3d 1427, 1447 (9th Cir. 1996) (holding that one conspirator should be held liable for other conspirator's refusal to sell power to plaintiff).

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied in its entirety.

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[24] REDACTED

[25] It is also noteworthy that the Complaints detail significant joint actions by the Defendants in furtherance of the scheme. For example, the baseless infringement suits filed to unlawfully delay generic competition were filed jointly by both Abbott and Fournier. See, e.g., DPC Cpt. at ¶ 65.

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CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2005, I electronically filed the foregoing (REDACTED) DIRECT PURCHASER PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' CONSOLIDATED TO DISMISS using CM/ECF, which will send notification of such filing to all registered participants, as follows:

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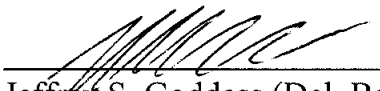

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